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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/487,359

01/19/2000

Dean A. Schaefer

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05/24/2004

CROMPTON, SEAGER & TUFTE, LLC
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EXAMINER

MAIORINO, ROZ

ART UNIT

PAPER NUMBER

3763

21

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/487,359

Applicant(s)

SCHAEFER ET AL.

Examiner

Roz Maiorino

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 and 23-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 23-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4, 6, 11, 13-15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No. 5057092 to Webster Jr.

Webster discloses a braided catheter with low modulus warp. Referring to FIG 2 this apparatus contains an inner tube 22 and outer tube 30 and an interwoven helical reinforcement layer 24 with an axial member 28. The reinforcement layer is located between the outer tube 30 and the inner tube 22. The inner and outer surfaces are free of protrusions caused by axial member 28.

The inner and outer walls 22 and 30 are made of flexible plastic material such as polyurethane. (Col.2, line 33) The axial member is made out of material with a level of flexibility, in which it allows for movement in relation to inner and outer tube. The helical members 24 are made of material having a high modulus of elasticity. Preferred helical members are made of stainless steel wire, although, depending on the application material such as Kevlar thread and modified polyethylene material may be used. (Col.2, lines 55-65)

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Webster does not teach a helical member such that the axial member is always disposed over the first helical member when the axial member crosses the first helical member, and beneath the second helical member when the axial member crosses the second helical member.

At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to have a helical member such that the axial member is always disposed over the first helical member when the axial member crosses the first helical member, and beneath the second helical member when the axial member crosses the second helical member, because applicant has not disclosed that the above cited limitation provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with a helical member such that the axial member is always disposed over the first helical member when the axial member crosses the first helical member, and beneath the second helical member when the axial member crosses the second helical member because they perform the same function.

Therefore it would have been an obvious matter of design choice to modify Webster to obtain the invention as specified in claim 1.

2. Claim 12 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No. 5057092 to Webster Jr. as applied to claim 1 above, and further in view of US Patent No.6042578 to Dinh et al.

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As mentioned above Webster discloses a braided catheter with low modulus warp.

Webster, however, does not teach the helical material comprising of Radiopaque material. Dinh discloses a catheter reinforcing braids with helical material comprising Radiopaque material. (Col.3, lines 30-40)

Therefore, it would have been obvious to one having ordinary skill in the art the time the invention was made to combine the two studies because to place a helical member coated with Radiopaque will allow the caregiver to follow the procedure with series of X-Rays, it gives the physician eyes inside the patients lumens. With any procedure in medicine being able to see which part of the body you are advancing up on is half the battle, if you don't have visualization it will increase the risk of injury to the patient 10 fold.

3. Claims 5, 7-9, 16, 17-20, 23, 25-26, 28-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S Patent No. 5057092 to Webster Jr, and further in view of US Patent No. 2003/0097119 to Garabedian et al.

As mentioned above Webster teaches the invention except for utilizing monofilament comprising of liquid crystal polymers in a flat ribbon. Garabedian teaches a monofilaments

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to have added Garabedian monofilament comprising to Webster's invention, because the monofilaments formation allows kink resistant.

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Allowable Subject Matter

Claims 10, 21, 24, 27 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 1-21, 23-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of U.S.

Patent No. 6709429. Although the conflicting claims are not identical, they are not patentably distinct from each other because the applicant has changed the scope of the claims in the new application.

Response to Arguments

5. Applicant's arguments filed 3-12-2004 have been fully considered but they are not persuasive. Applicant alleges that Webster although teaches all the limitations of the

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applicant's claims leads to increase stiffness of the catheter hence teaches away from the applicants invention. However the applicant has claimed "wherein the axial member limits elongation of the catheter under tension but does not substantially reduce catheter flexibility" (emphasis added). Therefore the applicant's invention does increase stiffness of the catheter via the axial member to limit the elongation of the catheter under tension, just like Webster does increase stiffness of the catheter. Although the applicant invention does affect flexibility to some level, the applicant's main argument is that his invention does not substantially affect flexibility. That argument is not persuasive, both Webster and the applicant increase stiffness and affect the flexibility of the catheter to some level.

Conclusion

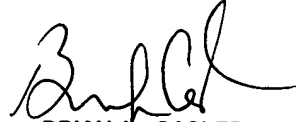
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roz Maiorino whose telephone number is 703-305-2336. The examiner can normally be reached on 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RM


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